DECLARATION OF DR. JOSEPH M. PATTI, PH.D. UNDER RULE 132		
	Application #	09/813,820
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	First Inventor	HOOK, Magnus
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	Examiner	Ford, Vanessa L.
	Docket #	P06357US02/BAS

Commissioner for Patents
P.O. Box 1450
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S I R:

I, Dr. Joseph M. Patti, Ph.D., declare and state as follows:

1. I am currently the Vice President of Clinical Research for Inhibitex, a company that specializes in products and research regarding extracellular matrix proteins including the "MSCRAMM®s" such as collagen binding proteins which are embodied in the present invention. In addition to being a co-inventor of the above-identified application, I am the inventor or co-inventor of numerous US Patents in this general field, including U.S. Pat. No. 6,288,214 for Collagen Binding Protein Compositions and Methods of Use, U.S. Pat. No. 6,680,195, for Extracellular matrix-binding proteins from Staphylococcus aureus, U.S. Pat. No. 6,685,943, Fibronectin binding protein compositions and methods of use, and U.S. Pat. No. 6,692,739, Staphylococcal immunotherapeutics via donor selection and donor stimulation. I am also the author or co-author of numerous journal articles in this field including my 1995 journal article cited by the Examiner in the above application and discussed below.

2. The above invention as presently claimed is directed to an antibody that binds to the M31 subregion of the collagen binding protein of *S. aureus,* this subregion having the sequence of amino acids 61 to 343 of the collagen binding protein. This subregion is a different

subregion than the one isolated as disclosed in my prior paper which is cited by the Examiner, namely Patti et al., *Journal of Biological Chemistry,* Vol. 270(20):12005-12011 (1995). In that paper, I disclosed isolation of the M17 subregion (amino acids 151-297) and **not** any antibodies generated against the 61-343 subregion known as M31. Accordingly, the Examiner's statement that my prior journal article "teach that antibodies were raised against the M31 collagen binding segments" (Official Action, page 11) is simply not true.

3. It appears that the Examiner's statement that my prior paper taught antibodies against the M31 subregion (61-343) must have been based on the assumption that antibodies raised against a lesser-included region (e.g., 151-297) would necessarily recognize or bind to a greater region (61-343). This assumption is also not true.

4. In fact, the present inventive group has actually carried out tests showing that contrary to the Examiner's arguments, monoclonal antibodies generated against the various subregions were not predictive of which other subregions could be recognized. Indeed, the tests as reflected in the attached Appendix, conducted with five different antibodies which were generated against and which recognized at least the M55 (50-329) region, showed that some of these antibodies did **not** recognize the native collagen receptor even though the native collagen receptor protein would have included the lesser M55 region which is the collagen binding domain of the collagen binding protein. In addition, a number of these antibodies did **not** recognize the M31 region. Further, these tests showed that **none** of the generated antibodies recognized the M17 subregion indicating that whatever epitopes are present on the isolated M17 region were not recognized by antibodies generated against a larger region.

5. Accordingly, the attached Appendix shows that antibodies generated against one particular subregion of the collagen binding protein do not necessarily recognize larger regions or lesser included regions, and thus the Examiner's assumption that my prior paper taught antibodies that bind to the M31 subregion is not true. In short, no antibodies generated against the M31 subregion (amino acids 61-343) are taught in my prior paper.

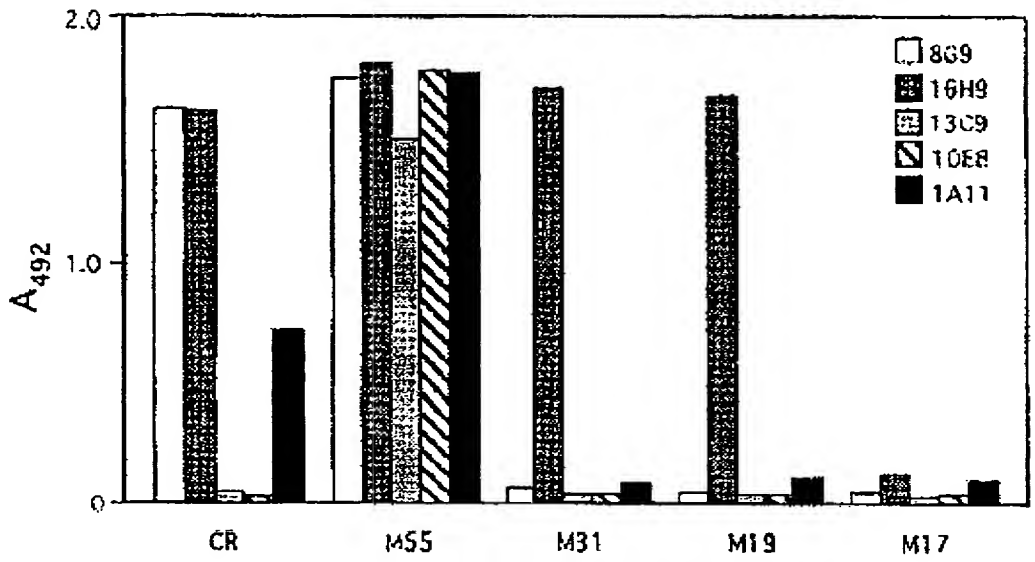
I hereby state that all statements made herein based on my own personal knowledge are true and correct and that all statements based on my information and belief are true and correct to the best of my knowledge, and further that all of these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

6/13/06
Date

Dr. Joseph M. Patti, Ph.D.

APPENDIX

ELISA analysis of immobilized recombinant constructs of collagen binding MSCRAMM



Five antibodies were analyzed by ELISA for their ability to bind portions of the collagen binding MSCRAMM. Antibody 16H9 recognized the fragment M55 (CBD 30-529), M31 (CBD 61-343) and M19 (CBD 151-318), but not M17 (151-297). The other four antibodies only recognized the largest portion of the collagen binding MSCRAMM. These data clearly demonstrate that antibody recognition of an epitope in a larger protein does not ensure that the antibody will also recognize a smaller portion of the same protein. CR= native collagen receptor from *S. aureus*.